00-126

TDH
TEXAS DEPARTMENT OF HEALTH

TEXAS DEPARTMENT OF HEALTH
AUSTIN, TEXAS
INTEROFFICE MEMORANDUM

TO: Herman Horn, Chief, Bureau of Regional/Local Health Operations
Regional Directors
Directors, Local Health Departments
Directors, Independent WIC Local Agencies

FROM: Barbara Keir, Director
Division of Public Health Nutrition and Education
Bureau of Nutrition Services

DATE: December 1, 2000

SUBJECT: Formula Conference Calls

Attached please find the script to the July 18, 2000 formula conference call on Concentrating Formulas, the Pediasure 50% Rule, and Low Iron Formula. We apologize for the lengthy delay in providing it to you. We are attaching the instructions/handouts developed for concentrating formula to 24 calories/ounce and 27 calories/ounce (English and Spanish) and next week will mail the measuring cups purchased for CPAs to use for demonstration.

In addition, we need to make a correction to the attachment that was provided for the October 3 conference call. At the bottom of page 6, a scoop of NeoSure shows 48 calories and it should be changed to 49.4 calories. Several agencies indicated that page 3 was missing from their attachments and it was also absent on the web page. It is now available on the web page.

Several of you requested the web site for the North American Society for Pediatric Gastroenterology and Nutrition's algorithm for Evaluation and Treatment of Constipation. It is: www.naspgn.org/constipation.pdf

We would appreciate your feedback concerning these formula sessions. Please feel free to share your thoughts about these conference calls by completing the attached survey. Fax or mail the completed survey to the attention of Roxanne Robison, CSHCN Consultant or Patti Fitch, Clinical Nutrition Coordinator. If you would like to order tapes from the July and/or October formula conference calls just make a note on the survey, and we will send them to you. If you have any questions, please contact us at (512) 458-7111 extension 3598.

Attachments

Formula Conference Call Survey

Local Agency #____ Name of Person Completing This Survey_____

Please take a few minutes to complete this survey. Your feedback is very important to help us plan for future phone conferences.

Since our conference calls began, we have covered the following topics:

12-30-2000 - Comparison of Next Step Soy, Prosobee, and Cow's Milk
02-29-2000 - Allergies in Infancy
05-09-2000 - Obtaining Formulas through Medicaid
07-1 8-2000 - Concentrating Formulas, Pediasure 50% Rule, and Low Iron Formula
10-03-2000 - Formulas for Premature Infants

___Our local agency participates in the conference calls
The staff who typically listens to the conference calls are:
RDS LDs Nutritionists ___LVNs ___WCS ___PAs ___RNs ___MDs

Our local agency does not participate in the conference calls because:
____We do not have enough time to participate in these calls
____Tuesday is a bad day for us
____The time slot to which we are assigned (10-1 1:30) is not a good time
____The time slot to which we are assigned (12:-1 :30) is not a good time
____The information is not appropriate for our staff
Other _____

Please provide us with any additional comments you have regarding the conference calls:

Do you have any suggestions for topics for future conference calls?_____

_____Please automatically send us an audio tape of all future conference calls

Return the survey by fax to (5 12) 458-7446
Or by mail to Texas WIC Program
Bureau of Nutrition Services
1100 West 49th Street
Austin TX 78756

Attention:Patti Fitch,Clinical Nutrition Coordinator or
Roxanne Robison, SHCN Consultant

Preparing Infant Formula to 24 Calories per Ounce

Sanitation

- Formula should be prepared with water that has been boiled for five minutes and cooled to insure proper sterilization. This includes bottled water.
- For infants who are older than 3 months, follow the instructions from the health care provider for the need to continue to boil the water used to prepare formula.
- Carefully clean pitcher, bottles, nipples and rings with hot and soapy water, then put the bottle, nipples and rings in a pot and cover with water. Bring to a boil for five minutes.

Preparing Powdered Infant Formula to 24 Calories per Ounce

- Use only the scoop provided in the can of formula.
- Fill the bottle or measuring cup to the 5 ounce mark with water then add 3 level unpacked scoops of powdered formula. (This makes about 5.5 ounces prepared formula.)

Preparing Concentrated Infant Formula to 24 Calories per Ounce

- Fill the pitcher with 13 ounces of formula (one can) and add 8.5 ounces of water. (This makes 21.5 ounces prepared formula.)

Preparación de la fórmula para bebis que contenga 24 calorias por onza

Medidas de higiene

- El agua para preparar la formula se hervirá por cinco minutos a fin de esterilizarla y luego se dejará enfriar. Este procedimiento es también para el agua embotellada.
- Para los bebés mayores de 3 meses, siga las instrucciones del profesional de la salud con relación a la necesidad de hervir el agua que se usa en la preparación de la formula.
- Limpie meticulosamente la jarra, los biberones, las mamaderas y los aros con agua caliente y jabón y luego ponga los biberones, las mamaderas y los aros en una olla con suficiente agua para cubrirlos. Caliente hasta que hierva por cinco minutos.

Preparación de fórmula en polvo para bebi que contenga 24 calorias por onza.

- Use sólo el cucharón incluido en la lata de la formula.
- Llene con agua el biberón o la taza de medir hasta la marca de 5 onzas y añada 3 cucharones, al ras, de formula en polvo. (Esto rinde aproximadamente 5.5 onzas de f órmula preparada.)

Fórmula concentrada para bebi que contenga 24 calorias por onza

- Llene la jarra con 13 onzas de formula (una lata) y añada 8.5 onzas de agua. (Rinde 21.5 onzas de formula preparada.)

Preparación de la fórmula para bebés que contenga 27 caiorias por onza

Medidas de higiene

- El agua para preparar la formula se hervir6 por cinco minutos a fin de esterilizarla y luego se dejará enfriar. Este procedimiento es también para el agua embotellada.
- Para los bebés mayores de 3 meses, siga las instrucciones del profesional de la salud con relación a la necesidad de hervir el agua que se usa en la preparación de la formula.
- Limpie meticulosamente la jarra, los biberones, las mamaderas y los aros con agua caliente y jabón y luego ponga los biberones, las mamaderas y los aros en una olla con suficiente agua para cubrirlos. Caliente hasta que hierva por 5 minutos.

Preparación de fórmula en poivo para bebi que contenga 27 caiorias por onza.

- Use sólo el cucharón incluido en la iata de la formula.
- Llene con agua ei biberón o la taza de medir hasta la marca de 4.25 onzas y añada 3 cucharones, al ras, de formula en polvo. (Esto rinde aproximadamente 5 onzas de formula preparada.)

Fórmula concentrada para bebk que contenga 27 caiorias por onza

- Llene la jarra con 13 onzas de formula (una iata) y añada 6 onzas de agua. (Rinde 19 onzas de formula preparada.)

Preparing Infant Formula to 27 Calories per Ounce

Sanitation

- Formula should be prepared with water that has been boiled for five minutes and cooled to insure proper sterilization. This includes bottled water.
- For infants who are older than 3 months, follow the instructions from the health care provider for the need to continue to boil the water used to prepare formula.
- Carefully clean pitcher, bottles, nipples and rings with hot and soapy water, then put the bottle, nipples and rings in a pot and cover with water. Bring to a boil for five minutes.

Preparing Powdered Infant Formula to 27 Calories per Ounce

- Use only the scoop provided in the can of formula.
- Fill the bottle or measuring cup to the 4.25 ounce mark with water then add 3 level unpacked scoops of powdered formula. (This makes about 5 ounces prepared formula.)

Preparing Concentrated Infant Formula to 27 Calories per Ounce

- Fill the pitcher with 13 ounces of formula (one can) and add 6 ounces of water. (This makes 19 ounces prepared formula.)

July 18, 2000
Formula Conference call
Concentrating Formulas, the Pediasure 50% Rule, and Low Iron Formula

Patti: As a follow up to the last conference call, we had a messed up tape. It did not work and I think it is my fault. That is what everybody keeps telling me, but I am not sure how I am to blame for that darn thing not working. But anyway, we do not have a transcript for it. We did mail out in last Friday's mail out a packet of information that included instructions for helping WIC participants get formula through Medicaid. It is a step-by-step instruction and then I think there is a form that can be used with the vendor that if you fill it out you have provided all the information that they would need. We did mail it out to you on last Friday's mail out and after looking it over, we feel it is comprehensive enough that if you go through and read the instructions, you have most of the information that we gave at the conference call. So I apologize for the problem, the mess up with the tapes and that there will not be any transcript available from that one, but I do think that the materials we provided probably will give you the majority of information that was shared.

Roxanne: One thing I want to say about the Medicaid forms that were mailed out last Friday, I have had a couple of calls on this. Do you remember the old WIC/Medicaid referral form that we sent out three or four years ago? Well, it is no longer in use. Some people are still using it or still think that we are using it to make sure that a participant gets their formula through WIC before they get it through Medicaid. The form was designed for that purpose. If a child qualified for both WIC and Medicaid, we wanted to get have WIC pay for their formula before Medicaid because WIC has more money than Medicaid, but we were told that if a child qualifies for both programs, then we cannot dictate where they get their formula from. It is really their choice, so we are not using that form anymore. And the form that was sent out on Friday is a different form although it kind of has a similar title. It is called a Request for Medicaid Formula or Medicaid Nutritional Products. This is the form to be faxed to the vendor, such as Medco or D&L, to obtain extra formula thru Medicaid that WIC cannot provide. So if you have any of those other forms left, just go ahead and ditch them because we are not using those anymore.

Patti: Do you want to go ahead and start off, Roxanne, with the concentrating formula?

Roxanne: Okay so now we will get into the topic of the day, which is concentrating formula to twenty-four calories per ounce. We have sent you two handouts on concentrating formula. The first handout describes the "Steps to Take When 24 Calorie Infant Formula is Prescribed". This sheet is for staff use. The next handout is called

"Preparing Infant Formula to 24 Calories Per Ounce", with the little baby bottles on it. This is the handout that goes to the care giver when you are giving the instructions on how to concentrate the formula. Now, why do they have two forms of Enfamil and Similac 24? They have a ready-to-feed and form and then you can make that formula by concentration, using the liquid concentrate or the powder. We ask that when you get a prescription for Enfamil 24 or Similac 24, that we have the care giver concentrate the formula using the powder or the liquid concentrate. The reason is because of cost. If we issue the three-ounce, ready-to-feed 24 calorie per ounce bottles, it costs us between four hundred and seven hundred dollars a month for one month's supply, depending on where we get it. So you know, it just makes sense for us to use our contract formula which costs us only pennies per can. Now there are a couple of circumstances where we would provide the ready-to-feed nursettes and those are the reasons that we would provide ready-to-feed formula for any other reason. The first instance is when a care giver is not capable, for some mental or physical disability, of preparing formula. Another reason would be if they have an unsafe or unsanitary water supply. For example, if they have well water that is not good for the baby. Maybe it has too high of a certain mineral content in it. Or for some reason they are not using their well water, for example, their water supply is not safe. Then we would issue the ready to feed. But normally we would just ask that they concentrate it. Now, why would a participant need to be on twenty-four calorie infant formula? Well there are several circumstances when it might be appropriate. One is when a baby may have an oral motor feeding difficulty. They might have a cleft lip or palette and really have to struggle to get that formula in. Maybe they are just tiring easily, because of having to really work so hard to feed. So you would want to concentrate the formula so they would have to take less volume and they would not have to have a feeding that lasts any longer than about thirty minutes. I saw a baby last week who required 24 calorie formula. It was a healthy, full term baby that just happened to weigh ten pounds and two ounces and because they were so tight in the uterus, he was born with a misaligned jaw. They worked with a lactation consultant for a few weeks and were not able to breast feed and so they went to bottle feeds and when I observed the infant feed, it took him up to an hour to take the entire bottle because of this jaw problem. So what we did was concentrate the formula so he would not have to take so long to feed. There are other conditions like congenital heart disease where they really have to struggle to feed. They tire easily. They may turn blue with feedings. They may have oxygen desaturation. So you would not want them to have prolonged feeding times either. There are certain conditions that just require more calories, like broncho pulmonary dysplasia where they bum a lot of calories trying to suck, swallow, and breathe. The increased cost of that, it is the same reason. You just want them to have a smaller volume with adequate calories. They just could require more calories in conditions like cystic fibrosis, AIDS or certain cancers. The first thing to do when we get a prescription for

"Preparing Infant Formula to 24 Calories Per Ounce", with the little baby bottles on it. This is the handout that goes to the care giver when you are giving the instructions on how to concentrate the formula. Now, why do they have two forms of Enfamil and Similac 24? They have a ready-to-feed and form and then you can make that formula by concentration, using the liquid concentrate or the powder. We ask that when you get a prescription for Enfamil 24 or Similac 24, that we have the care giver concentrate the formula using the powder or the liquid concentrate. The reason is because of cost. If we issue the three-ounce, ready-to-feed 24 calorie per ounce bottles, it costs us between four hundred and seven hundred dollars a month for one month's supply, depending on where we get it. So you know, it just makes sense for us to use our contract formula which costs us only pennies per can. Now there are a couple of circumstances where we would provide the ready-to-feed nursettes and those are the reasons that we would provide ready-to-feed formula for any other reason. The first instance is when a care giver is not capable, for some mental or physical disability, of preparing formula. Another reason would be if they have an unsafe or unsanitary water supply. For example, if they have well water that is not good for the baby. Maybe it has too high of a certain mineral content in it. Or for some reason they are not using their well water, for example, their water supply is not safe. Then we would issue the ready to feed. But normally we would just ask that they concentrate it. Now, why would a participant need to be on twenty-four calorie infant formula? Well there are several circumstances when it might be appropriate. One is when a baby may have an oral motor feeding difficulty. They might have a cleft lip or palette and really have to struggle to get that formula in. Maybe they are just tiring easily, because of having to really work so hard to feed. So you would want to concentrate the formula so they would have to take less volume and they would not have to have a feeding that lasts any longer than about thirty minutes. I saw a baby last week who required 24 calorie formula. It was a healthy, full term baby that just happened to weigh ten pounds and two ounces and because they were so tight in the uterus, he was born with a misaligned jaw. They worked with a lactation consultant for a few weeks and were not able to breast feed and so they went to bottle feeds and when I observed the infant feed, it took him up to an hour to take the entire bottle because of this jaw problem. So what we did was concentrate the formula so he would not have to take so long to feed. There are other conditions like congenital heart disease where they really have to struggle to feed. They tire easily. They may turn blue with feedings. They may have oxygen desaturation. So you would not want them to have prolonged feeding times either. There are certain conditions that just require more calories, like broncho pulmonary dysplasia where they bum a lot of calories trying to suck, swallow, and breathe. The increased cost of that, it is the same reason. You just want them to have a smaller volume with adequate calories. They just could require more calories in conditions like cystic fibrosis, AIDS or certain cancers. The first thing to do when we get a prescription for

Enfamil or Similac 24, is to make sure that it is what the physician really wants. Sometimes we have these premature infants that are less than eight pounds and we get a prescription for Enfamil 24 or Similac 24 and the physician really wants is Enfamil Premature 24 or Similac Special Care 24. They just have not put the full name of the formula down. So if you have a premature infant that weighs less than eight pounds, you need to call to verify the diet order. Is that really what they want? And the correct formula it is documented on the prescription form. Now Enfamil Premature 24 is not to be used in an infant over five and a half pounds and Similac Special Care is not to be used in an infant over eight pounds. At that weight, they start taking more formula and these formulas have higher levels of vitamins and some minerals and they may get a vitamin toxicity at that higher intake. It is not to say that they would never take one of these formulas, but usually that is done by the neonatologist who is monitoring the baby very closely. They are following-up to make sure the infant does not get into trouble. It is usually not done by the pediatrician. Say they have been discharged from the hospital and they are on a step-down formula like NeoSure or EnfaCare and are not gaining weight very well. So the pediatrician wants to put them on a premature formula. That is probably not appropriate. They probably want to concentrate that step-down formula to a higher calorie per ounce, rather than go with the premature formula, because they will not be monitoring their blood labs very often as an outpatient So once you have established that the physician really does want Enfamil 24 or Similac 24, the next thing to do is to call the prescriptive authority, be it the doctor or the physician's assistant or whatever and explain WIC policy. That we do not provide the ready-to-feed variety except for those certain circumstances and that we would like to provide instructions for the care giver to concentrate that formula. More than likely, they are not going to have a problem with that and we would go ahead and instruct the care giver on how to prepare the formula. The best way to instruct them is to demonstrate how it is done. You want to make sure that they leave the office really understanding how to correctly mix the formula. We do not want to take a chance that they are over-diluting it or under-diluting it. Check with the care giver to see if they have appropriate measuring tools at home, like measuring cups and not that they are just using a coffee cup, for example, to measure. If they do not have appropriate measuring tools then, what we have decided to do is provide you all with some plastic measuring cups that they use in the hospital, actually for urine collection. But they are really nice. They have the little c.c. increments and half ounce and ounce increments on it and they go up to eight ounces. They cost like ten cents apiece and it will be a nice tool for you all to have to give to the parent. Now in the meantime, if you do not have the measuring tools to use, we ask that you go ahead and use their baby bottle. This is not ideal because those baby bottles are not exact measuring tools. They could be a half ounce off here and there. So they are not ideal but, if that is all you have available, it is better than nothing until we can get something better.

The next thing to do is to document that you have provided those instructions to them and that you talked to the physician. You can copy the handout that you give to the care giver and put it in the chart as your documentation. If you will look at that next form, it is a little handout for the parent that Matt made up, and it shows you how to go about concentrating either the powdered infant formula or the liquid concentrate to twenty-four calories per ounce. Now I know that some of these instructions may be different than what you have been used to. We had someone in the morning session that faxed us a form that they have been using that showed that what we did for the powdered formula actually concentrated it to twenty-two calorie per ounce. Well that form was incorrect. The instructions for powdered formula here will make twenty-four calories per ounce. You want to till the bottle or the measuring cup to the five ounce mark and then add the unpacked leveled scoops of powdered Enfamil on top of the five ounces of water and that will make a final volume of about five and a half ounces. You may have seen other recipes for concentrating liquid concentrate to twenty-four calories per ounce. I know Mead Johnson has their literature that says to add nine ounces of water instead of the eight and a half to make twenty-four calorie per ounce and I checked with some hospitals and some of them are using eight ounces. Some use eight and a half. Some use nine. There is not a lot of consistency here so we had to pick something. And what is really the most accurate is to use the eight and a half ounces of water. If you add nine ounces of water, you are actually going to get a 23.6 calorie per ounce formula. If you add eight and a half ounces of water, you are going to get 24.1 calorie per ounce. So since we are asking that they do not use the ready-to-feed, which is twenty-four calories per ounce, we want it to be as accurate as possible. As close to the real twenty-four calories per ounce as possible. Does anybody have any questions so far?

Fern: This is Project 76-67. Will we be getting the instructions of preparing the formula to twenty-four calories per ounce in Spanish also?

Roxanne: Yes, we had that question earlier and yes, we will be sending that out. We just wanted to get something out to you all before this conference call. I think that is a really good idea. One thing you might put on this form that you give to the care giver, is your phone number because they may have questions when they come home on how to prepare it, so I would always give them a way to contact you. Are there any questions about twenty-four cal formula?

Fern: Yes, this is Gwen from Project 48. When are we going to start implementing these rules?

Roxanne: Right away.

Fern: Right away? Okay.

Roxanne: I checked the formula policy this morning and actually Enfami124 or Similac 24 is not on there. I guess it was a level four formula. If you got a request for that you were to call the state office. This was going to be included in the new formula policy that you all have already reviewed and sent back to us. But turns out, we are not going to be sending those new formula policies out until January or March. Patti is going to talk a little bit about that later, but we wanted to send some of these guidelines out ahead of time like this one here.

Fern: This is Charlene from Project 7.

Roxanne: Yes Charlene?

Fern: We just dialed in so I do have a question. I noticed in that second paragraph on the steps on the twenty-four calorie formula.

Roxanne: Yes?

Fern: You all are stating that by concentrating the formula, it will be, it will provide an identical product?

Roxanne: Yes.

Fern: Okay, so there really is no difference whatsoever? Because I think at one time, I want to say Jay and I were talking about this and it seemed like there was a higher mineral content to the Enfamil Premature 24 as opposed to just concentrating the regular Enfamil.

Roxanne: Right, well Enfamil Premature 24 is a totally different product. It does have a higher mineral content, but there is an Enfamil24 ready-to-feed that is exactly the same product as concentrating either the powder or liquid concentrate to twenty-four calories per ounce.

Fern: I see what you are saying. So if they are above that weight limit, then we can concentrate the regular Enfamil or do we prescribe the Enfamil 24?

Roxanne: Well, you are going to have to check with whoever wrote the prescription and let them know that you do not use the premature formulas over that weight limit.

Fern: Right.

Roxanne: A lot of times they will just say go with the twenty-four calorie per ounce by concentration. Or they probably, if it is a premature infant, will use one of the step-down formulas like EnfaCare or NeoSure. And they can concentrate that to twenty-four calories per ounce too.

Fern: Okay. I see what you are saying though, because this is confusing. I was thinking we were talking about the same formula, but we are talking about two different formulas.

Roxanne: Right, and doctors get confused all the time. That is why it is important to contact them and make sure that what they are ordering is really what they want.

Fern: Alright. Thank you.

Roxanne: Okay.

Fern: Roxanne?

Roxanne: Yes.

Fern: Project 29. This is Jeanie. I have a question.

Roxanne: Okay.

Fern: Did you say earlier that the Enfamil Premature 24 is a level four formula?

Roxanne: I believe that is a level two. The premature formulas are a level two.

Fern: Okay. And then my second question was if it is just for a higher concentration like, concentrating the Enfamil to twenty-four calories, we also need a prescription from the doctor, is that right?

Roxanne: Yes.

Fern: So it is not just if the mother tells us the doctor said?

Roxanne: Oh no, you need a prescription.

Fern: Okay, thank you.

Roxanne: Okay. Anybody else?

Patti: Those are good clarification questions, does anybody have anything else? I also wanted to add that Matt had been in contact with Mead Johnson to get something in writing concerning the product, once you have concentrated it, as compared to the product on the market that is twenty-four calorie nursettes, and we do have a letter here from Mead Johnson that tells you that what is in the nursette bottles is the very same formula as what you would be concentrating Enfamil to twenty-four calories. So if any of you ever need that as a backup to work with a physician, please let us know. We can zip you a copy of it.

Roxanne: Oh, I left out one thing here. When a participant is using concentrated Enfami124, if we are having them use our contract formula, we can only issue the thirty-one cans a month or the eight pounds of the powder. So when they concentrate it, they are going to actually end up with fewer ounces than if we were to issue the ready-to-feed Enfami124. So you can give them six cans extra of liquid concentrate from your sample stock or one extra can of powder from your sample stock. Now you would not want to issue that on a voucher as extra cans, because that would be going over the limit that USDA says the WIC program can issue each month. But you can use your sample formula. We checked with USDA and they agreed that would be an appropriate use of sample formula. I would encourage you to have the participant take the liquid concentrate, because you are going to end up with more ounces than if you issue one extra can of powder. The way we came up with those numbers of cans is that an infant is allowed eight hundred and six ounces of ready-to-feed formula and with your six extra cans of liquid concentrate, they are going to get to the eight hundred and six ounces. If we were to issue two cans of powder, they would go over the reconstituted amount of eight hundred and six ounces. So we cut that off at one can. But they will be getting less ounces if you give them the powdered formula. Does that make sense? They will actually be getting forty-two more ounces with the liquid concentrate than what the powder will yield. We had a doctor tell us one time that he did not want us to concentrate the formula, he wanted the ready-to-feed, because he knew that they would be getting less total ounces if we did it that way. So you know, I think he has a good point.

Fern: Hi, this is Sue at Project 56.

Roxanne: Yes.

Fern: I just had a comment/question about the osmolality of the under-diluted formulas that we need to make very certain the babies do not have any kidney problems at all.

Roxanne: Right. And you know...

Patti: Repeat her comment to them.

Roxanne: Her comment was that when you are increasing the concentration you are also increasing the renal solute load and so you would want to make sure that the baby does not have any kidney problems. That should be coming from the doctor. But it is a good point. Okay, if you all do not have any other questions about that, we can go on to the next topic, which is the fifty percent rule for PediaSure or any other nutritionally complete product. Say Nutren Jr., Resource Just for Kids, Kindercal or PediaSure. We have had a rule for quite a while that stated that those products had to make up more than fifty percent of the child's calories. And we have relaxed that rule because there are some children that will still need to be on formula and it will not make up fifty percent of their calories. I think at one point, we had that rule because we felt like the child would benefit more from the child package than they would from the formula when they were taking less than fifty percent of that from calories. But actually some of those formulas are pretty expensive and that puts a burden on the parent to have to buy those expensive formulas when the child really cannot meet their nutritional needs without it. An example would be a child that is weaning from a tube feeding, that maybe use to get all their calories from tube feeding and now they are eating orally pretty well, but they are not quite there to eat all their needs orally. They may still get a can or two of PediaSure, by tube or orally, just to be able to meet their needs. Well we would not want to penalize them because they are doing better and eating orally. We would not want to take their formula away. The idea is to get them totally weaned at their own pace. Another example is a child that may have really high nutritional needs, that eats orally during the day, but gets a supplement tube feeding during the night. And that tube feeding may make up less than fifty percent of their calories. Again, we do not want to penalize that family just because their child is doing better. So I know that is not in our current policy, so you will have to call the state office to get approval for issuance. Anybody have any comments or questions?

Fern: That is going to be stated in the new formula issuance policies?

Roxanne: Yes, it will be.

Fern: That will be clarified then?

Roxanne: Yes.

Fern: So we can just call the state office for approval.

Roxanne: Call the state office for approval.

Patti: Okay, are there any other comments on the fifty percent rule?

Fern: Patti, I have a comment. I am from Project 54.

Patti: Yes.

Fern: So you are saying that if, because we have some that are right on the border. It is hard to almost tell sometimes if they are forty or fifty percent, the doctor wants it to prevent failure to thrive, that the child is already way below the fifth percentile, so if it is borderline there and it is a gray area, you are saying to still, it needs to be a level four?

Patti: No, if you just check with the state on it, because basically what we are doing, is you are talking about the exact examples that we have gotten concerned about were slipping through the cracks. They really needed the formula. It is one of those issues where right on the border is not good enough. We need to be providing it. If you will call the state on those, we will approve it from up here. I do not even think it is a level four in the new policies.

Roxanne: Well anything that you have to call the state about is a level four. So...

Patti: Well, but I was talking about in the new ones.

Roxanne: Right, oh, in the new policy, I think it is a level two.

Patti: Yes, when we get that policy out. And we will talk about the policy process here in a few minutes.

Roxanne: I think that people had some difficulty too, determining whether it did make up fifty percent or more of their calories and people were doing it a lot of different ways and there was not really any consistency to it so it is just a bad rule. But it is getting better.

Patti: Yes, we are trying fix it so if you have anybody that you think is one of those borderline cases or it is just not real clear, call us and let us run it through and see what we can do about it.

Roxanne: It will typically have to be a medical reason. It is not just because they are picky eaters and they are not really meeting all their calorie needs because they are a one to three year old that is a picky eater. It should be a medical reason.

Patti: Okay. Are there any more comments along those lines? Well our next topic is the low iron formula and we just wanted to walk you through a process. As you know, we have a non-contract formula issuance policy which states real clearly that we do not issue low iron formula for anything but hemolytic anemia and thalassemiamajor. We have talked among ourselves and decided we need to let you all know that we have approved low iron formula for babies who are in terminal conditions and the physician is requesting it just to ease the process and it is one that is working for them and they do not want to change them. We have, from the state office, approved low iron formula for some babies who are terminal. So I needed you all to know that, because we do not have it in writing anywhere. So if this issue comes up, please feel free to call us. We just wanted to kind of go through this process with you to give you more support and background on our stand against issuing low iron formula. So Roxanne, you want to...

Roxanne: Yes. You received an article in your handout today called the "Tragedy of Iron Deficiency During Infancy and Early Childhood". And that is actually an editorial comment in the same journal as the original research article entitled, "Severe Iron Deficiency Anemia in Young Children". So I wanted to review that article a little bit with you all. I think a lot of times we hear from parents and from physicians and we get a lot ofpressure to issue low iron formula for constipation and sometimes we just feel like, let's give it to them. It will make everybody happy. What is the problem? This is what the doctor wants. This is just a good reminder. This article came out last year in the Journal of Pediatrics and summarizes why we do not issue low iron formula for infants except under very rare circumstances. This article is written by a group of hematologists at a children's hospital in Philadelphia, Pennsylvania. They went back and reviewed charts of children that were diagnosed with iron deficiency anemia from 1978 to 1997. They define severe iron deficiency anemia as hemoglobin less than 6.0 grams per deciliter. Applicants can qualify for WIC if they have a hemoglobin less than 11 .O grams per deciliter as infants and then anything less than 11.1 grams per deciliter for two to five year olds. So they had pretty severe iron deficiency. They just wanted to look at those kids that had iron deficiency anemia from dietary reasons. So they eliminated the children that had blood loss from other diseases, like Crone's disease or excessive menstrual blood loss, and what they found was that the mean age of diagnosis for nutritional deficiency was 1.8 years. They found that of the fifty-five children, forty-seven percent were white, forty percent were Southeast Asian, and five percent were African American. They do not have a large Hispanic population there, so it did not identify any Hispanics, but we know that about twenty-five percent of Hispanics are iron deficient. It was interesting because these children were not going to the doctor because they had symptoms of iron deficiency. Two of them were identified in a WIC clinic. Twelve of them were

identified in a well child checkup and the remainder were identified because they had blood work for some other illness that was going on. Acute illness. What the diets looked like was that most of them had received iron fortified infant formula as infants, although cow's milk was started at a mean age of 10.4 months. But the age range that they were given cow's milk was from birth to twenty-four months. Three of them were breast fed and one drank a low iron formula. Only nine of the children had diets that regularly included meat or iron fortified cereals. And thirty-two of the forty-two patients that they had milk consumption data on, were drinking more than a quart of cow's milk a day.And one-third of these children had blood loss from excessive cow's milk intake. What the authors were saying in this study was that even though we have eliminated a lot of iron deficiency anemia, it is still pretty prevalent and the major cause of it is dietary iron deficiency. Also, that it occurs mainly between the ages of one and three years when infants go off of iron fortified formula and on to cow's milk. It also occurs because of the early introduction of cow's milk before one year of age. And as far as the large number, only one percent of their population is Southeast Asian in Philadelphia, but forty percent of the children with iron deficiency anemia were of Southeast Asian origin. The physician's thought that the reason for this is they have a language barrier and they are not understanding diet counseling. They also had diets that consisted of a lot of milk and they ate mainly soup with very little meat in it and rice, and they also had prolonged bottle feeding. So if they were drinking a lot of infant formula and they were still on the bottle at a year, and they switched to cow's milk, they were drinking a lot of cow's milk over a year of age. Iron deficiency anemia is really a severe condition and we do not want to create iron deficiency because of a constipation problem. Matt is going to talk a little bit more about the article that you were given in your packet and that has more to do with why iron deficiency anemia is such a tragedy.

Matt: The editorial in the Journal of Pediatrics from October 1999 is part of your handout packet. The author talks about the tragedy of iron deficiency, the fact that so many children suffer iron deficiency from improper nutritional practices and these nutritional practices result in irreversible brain damage and other conditions that are completely preventable. The author talks about not providing whole cow's milk before one year of age and encouraging breast feeding, and if parents choose not to breast feed, using an iron fortified formula and iron fortified infant cereal after four months of age. After one year of age only providing limited amounts of whole cow's milk, about sixteen ounces per day You can continue to provide iron fortified infant cereals or a cereal that is a good source of iron. Also, encourage intake of meat, poultry, vegetables such as beans after one year of age.

Patti: You want to talk about the ***(inaudible).***

Roxanne: Yes. Another thing that was interesting about the article was that these hematologists that have these children with iron deficiency anemia referred to their practice, maybe they do not get in to see them for a couple of months, but in the meantime, their pediatrician has put them on a vitamin mineral supplement, like a child's chewable tablet or like a Poly-Vi-Sol with iron. They are saying that these are not really providing therapeutic levels for a child with iron deficiency anemia. They really need to have the higher intakes, like Ferrinsol would provide. Just like pure iron drops. And so you might see children at the WIC clinic who are iron deficient and are being treated with those chewable vitamin supplements. Well they are saying that that is really not appropriate. They need to be on iron drops and not just Poly-Vi-Sol with iron. Another concern is lead poisoning. A lot of children with iron deficiency anemia will exhibit some behaviors associated with PICA where they eat of non-food items such as paint chips or newspaper. I had a child that like to chew on the end of a mop. The mop strings. They could get sources of lead in their diet and if they are anemic, they absorb lead better. This could lead to a lead toxicity. But the tragedy is that all of this is totally preventable by providing iron in the diet. This is why we are really strict about not issuing low iron formula. Because we could give them low iron formula and they are not showing as anemic, but it sets the stage for their one to three year old stage of life, where they normally develop iron deficiency anemia. And I know you all have heard this a lot, but I think it helps to hear it again, we really have not eliminated the problem and there are a lot of other ways to treat constipation, rather than putting a child on a low iron formula. Would you rather have a child that is constipated or a child with irreversible brain damage or loss of I.Q. points that, even when treated with iron therapy, the effects are irreversible. So anyway.

Patti: I think Matt did a run on the numbers of how many people we actually have on low iron formula.

Matt: The monthly issuance of iron fortified formula is generally low. Between nine and fourteen issuances per month. What we are requesting is that you just go back and double-check the reason for issuance to make sure it falls within our guidelines of hemolytic anemia, thalassemia major or in rare instances such as a child that is terminally ill.

Patti: Again, we are providing you with this information just to support the stand that we have taken and that you all have done such a good job on of not issuing the low iron formula. But I think it helps to be armed with the arguments for the physician and this article is real specific and real clear that there is really no excuse for issuing low iron formula because you have a kid with constipation. This just supports what you all have been doing and gives you some ammunition if you need it for turning those

requests down. I think we should move on now to the next topic which is our formula module. Roxanne, you were going to speak to that?

Roxanne: Yes, I just wanted to let you all know that there are more formula modules if you need more. You got a memo in June about WCS's and CPA's, oh, we are going to stop just for a second because we have to turn the tape over.
(End of Side A.)

Roxanne: Okay. We are ready. Just to let you all know that there are more basic infant formula modules available and that a memo was sent out in June that requires all CPA's and WCS's to have completed the module because monitoring will begin on that in October of 2000. I think that was all I wanted to say about that. Did you all have any questions about the formula module?

Fern: This is Gwen from Project 48. And I did fax over an order form, because we have never received the modules.

Roxanne: Oh, you have not?

Fern: And I faxed over the order form, I think I spoke with, is it Mimi that I faxed it to?

Roxanne: Right.

Fern: And I spoke with her again over the phone, but I still have not received them.

Roxarme: What project are you with?

Patti: 48.

Roxanne: 48, okay.

Patti: We can follow that up and see what is going on. Are there any other comments? Roxanne, did you want to talk a little bit about that advanced formula?

Roxanne: Oh, just to let you all know that I am working on what is going to be known as the advanced formula module. It includes all the formulas that are not in the basic formula module. And that is going to be quite a lengthy process, because there are a lot of formulas out there. What we thought we would do instead of waiting until the whole thing is completed is send it to you all in sections as it is completed. And then we would use these conference calls every other month to review the section that has been completed and then send it out to you all. The next time we meet in September,

the topic would be on premature infant formulas and I hope to have that completed and sent out to you all by that time and then as we go along, you can add that to your formula notebook along with your basic formula module that is already in there. By the way, I hope you all are working on your formula notebooks because topics like today, the twenty-four calorie formula is a really good thing to put in your formula notebooks so it is all in one place and when you go to approve formulas or need some information, you have it in the formula resource book. Like the Medicaid letter that we sent out last Friday, I hope you all will take that and also put that in your formula resource book.

Patti: Okay.

Roxanne: Okay, I think Patti is going to talk about the status of our non-contract formula policy.

Patti: Or the non-status of our non-contract formula policy. Basically, just to give you all a quick update and not belabor the issue, we had run into some problems in that we have recently, within the last year, been required to run every policy change through the Board of Health and, to make a long story short, what we are going to do is to pull our policy manual out of rules, out of the rule making process, and only leave in the rule making process those policies that have public impact. Things like how do you get to be a WIC vendor? What are the sanctions for WIC vendors? How does the WIC program approve foods? Those things that would have financial and public impact, we will leave in the rules process. But all the rest are procedures which is what most of our manual is made up of, will be out of that process and we can then have an easier time at keeping things updated and providing you with things without having to go through this additional step that we have been working through with the Board of Health. Of course, our policies and procedures still have to be approved through USDA. But this is hopefully a more time saving process. It is just that in order to get it into effect, as I understand from Valerie Wolf, it will probably be March or April, before we will be able to send out these policies that got stuck in never, never land. And the non-contract formula policy was one. There were, I think ten or fifteen that we were trying to process that ended up on hold and so we do apologize for that, but once we can fight this whole issue out, I think our processes will be a lot easier. And in the meantime, what we are wanting to do with some of these issues, things that Roxanne has brought to your attention and in some of the other areas, is we will probably send out guideline memos so that you all can go ahead and implement things, instead of having to wait until March or April to do so. So we are working on the whole issue and you all were so good about giving us feedback on that non-contract formula policy and just to let you know, we really did

finish with it, and it really does look good and I think it is really something you will' be happy with. It just got hung up in...

Roxanne: In the bureaucracy.

Patti: Yes. So that is kind of just an update on that and that is why you all have not seen it. But we will try to send out things that would make life easier on you all and in a guidance type of format so that you are able to go ahead and implement some of this stuff. Talking about confusing, Roxanne is going to talk to you a little bit about formula companies.

Roxanne: Yes. This came up after we sent out the agenda for the conference call, but PediaSure has been reformulated. There are now going to be two varieties of PediaSure available. There is going to be the original PediaSure that we are used to and then there is going to be the institutional variety. It is only going to be available in hospitals and perhaps in some DME companies like Medco and D&L. They have reformulated it to make it sweeter and on the new label, which will be on the shelves sometime this summer. It says, New Kid Approved Taste. What has happened is they have made it sweeter. It has increased the osmolality which has a lot to do with how a child tolerates a formula. I am not so concerned about normal healthy kids, but our kids that are on tube feedings and some children with special health care needs may not tolerate that increase in osmolality. Serum osmolality in your body is about 280 to 320 and you want your tube feedings to be as close to serum osmolality as possible. It is called iso-osmolar. PediaSure use to have an osmolality of 335. The new formulation has 420 milliosmoles per kilogram of water, so it is considerably higher. The worst change has come with the chocolate. The original was 365 and the new formulation is 520. So most of our children that are on tube feedings are on just plain vanilla. However, when they go to the grocery store and they do not have all the cans of vanilla that they need, sometimes they will pick up different flavors and that is going to be the problem, if they pick up chocolate in particular. They may even have a problem with just the plain vanilla. Some may not, but some may. Signs of intolerance could include diarrhea, increased reflux or vomiting. If you have a child that has been on PediaSure and all of a sudden you are getting complaints of intolerance, that may well be the reason. What I would do in that case is call one of the DME companies. Do not send them to HEB anymore to get the formula. Call D&L. Call Medco and see if you can get the institutional variety shipped to that participant. I hate that they have these two different formulas because it just makes everything very confusing and it is more costly for us when we use DME companies to send out formula. But for some of those kids I think is it going to be necessary. You could also consider a different type of tube feeding formula such as Nutren Jr. Resource Just for Kids would not be an option because it also has a higher

osmolality. I was going to say Kindercal, but guess what, they have reformulated their product too. They are going to have two varieties, an institutional variety and a retail variety that is sweeter. Kindercal used to come in just plain vanilla with fiber. Now they are going to have it with and without fiber and they are going to have chocolate and vanilla. It is going to be really confusing and I am not really happy with the formula companies. I am going to write them and tell them so. This has made our lives miserable.

Patti: So there!

Roxanne: And I think there are a lot of other people upset about it too. Because they are hitting those larger markets for the normal, healthy kids. Kind of like they are marketing Ensure now.

Patti: And we will try to pursue with the drop ship companies, that they will allow us to purchase the institutional products.

Roxanne: Well I did call D&L and they said that they only get the institutional varieties. But if I were you I would make sure that what they are shipping out says "not for retail sale: on the can. Okay. Any other comments?

Patti: Roxanne is sending out something on Friday concerning the PediaSure and then next week we will try to ship out the other thing about the Kindercal. When you all get the information if you will just stick it in your formula notebooks and use it as a reference source so that you can see what you are up against when you start running into problems with trying to get the right thing, for the right kid, for the right circumstance, in the right place, for the right amount of money, of course.

Roxanne: And I hope you do not run out of room in your formula resource notebook one of these days.

Matt : I will make a reference in the next comprehensive formula listing that there are now two different types of PediaSure and the Kindercal. The retail and the institutional and try to break it down by osmolality.

Patti: Right. Okay that would be a good idea.

Roxanne: And when is that going out Matt?

Matt: Soon.

Roxanne: The new resource list is going to be out soon?.

Matt: The semi-quarterly update.

Roxanne: So then you all can replace that one that you have in your resource notebook now, the old listing.

Matt: The April 2000 listing.

Patti: Right. Okay do you all have any questions about any of this information? About the formula listing, about . ..?

Fern: My name is Jo Miller and I am from Project 66.

Patti: Yes.

Fern: And I had a child the other day that was in that had lost a lot of weight and being supplemented with PediaSure and I talked to Liz and she brought up about the Carnation Instant Breakfast ***(inaudible)*** and about where you could ***(inaudible)*** they might rather have the full package ***(inaudible)*** than buy the Carnation Instant packages with food stamps. And I wondered if you, do you have any information on the dilution of that or the osmolality of that?

Roxanne: Carnation Instant Breakfast is available in a ready-to-feed form and it has always been available in the individual envelopes in different flavors and it is also available in canisters. It does have a lot higher osmolality because they use sucrose, table sugar, rather than some of the corn syrup solids and other carbohydrates that make it lower osmolality. It would not be for a child that has problems with tolerance on increased osmolality because that has got a pretty high osmolality. But it would be appropriate for those kids that want that the doctor says they need supplements for poor weight gain. That they do not have any medical problems, just have some poor weight gain. That would be appropriate and that way they could get the child packet with the milk and then they could buy the Carnation Instant Breakfast. It is a lot cheaper than PediaSure.

Fern: I thought that was an excellent idea and I had real good response.

Roxanne: Good.

Patti: Well good. Maybe Liz is listening and she can be just smiling real big right now. Any other comments or questions? Okay, well let's talk about the next formula conference call. As Roxanne indicated earlier, it will probably be over premature formulas and we hope to send you some handouts and things to review prior to the

call. We have looked at out calendars and have tentatively set it for September 19; 2000, which is Tuesday and it will be the same times. Ten o'clock and a noon. Is that right, ten? Ten-thirty? Ten. Everybody mark it on your calendars and unless you know of something huge that is going to be happening on the nineteenth, that would affect a number of us, we will probably be sticking with that date. Okay. I did not hear any comments, any major complaints, any warning, so we will go with that. If you have any other questions, speak now or forever hold your peace.